Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

In 2010, CDRH held three Town Hall meetings in Minneapolis, MN; Boston, MA; and Los Angeles, CA to provide the public with a new venue to discuss issues of interest with the Center. Any member of the public was invited to provide comments to or ask questions of CDRH participants. Due to the positive feedback we received for holding these meetings we plan to continue this activity in 2011 in three different locations.

II. Public Meeting

The objective of this public meeting is to engage in a dialogue about issues that are of importance to the public.

The public meeting will open with an introduction of CDRH Senior Staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will describe CDRH's Strategic Priorities for 2011. Members of the public will then be given the opportunity to present comments to CDRH Senior Staff followed by a Question and Answer session during which any member of the public may ask questions of the CDRH Senior Staff on any topic of interest.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: February 1, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–2490 Filed 2–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Industry Exchange Workshop on Food and Drug Administration Drug and Device Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Southwest Regional Office, in co-sponsorship with the Association of Food and Drug Officials (AFDO), the Mid-Continental Association of Food and Drug Officials (MCAFDO), and the FDA Medical Device Industry Coalition, is announcing a public workshop entitled "The Future of Medical Products Regulation: Ensuring Safety and Integrity in a Global Market". This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

Date and Time: The public workshop will be held on June 20 and 21, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Marriott Dallas/Plano at Legacy Town Center, Plano, Texas, 7120 Dallas Pkwy., Plano, Texas 75024, 972–473–6444, or toll-free 888–236–2427.

Attendees are responsible for their own accommodations. To make reservations at the Marriott Dallas/Plano at Legacy Town Center, at the reduced conference rate, contact the Marriott Dallas/Plano at Legacy Town Center before May 20, 2011, citing meeting code "AFDO Conference".

Contact: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, Texas 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *David.Arvelo@fda.hhs.gov.*

Registration: You are encouraged to register by May 24, 2011. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

COST OF REGISTRATION

Government (AFDO/Mid-Continental AFDO Member)	$425.00
Government (Non-Member):	525.00
Non-Government (AFDO/MCAFDO Member)	425.00
Non-Government (Non-Member)	525.00
To be added to registration fee for public workshop registration postmarked after May 24, 2011	100.00

If you need special accommodations due to a disability, please contact David Arvelo (*see Contact*) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to "AFDO". Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at

717–757–2888, FAX: 717–650–3650, or e-mail: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

- Globalization, Imports, and Supplier Controls,
- Medical Product Theft and Criminal Investigations,
- Proposed Changes to the 510(K) Review Process,
- Health Fraud,
- Streamlining the FDA Enforcement Process,
- The Future of Medical Products Regulation,
- Medical Devices in Canada,
- The Freedom of Information Act,
- Medical Product Complaint Investigations,
- Writing Corrective and Preventive Actions Procedures and Documents to Reflect Compliance Initiatives, and
- Top Ten FDA–483 Objectionable Observations.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2458 Filed 2–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Revision to Proposed Collection; Comment Request; The National Children's Study (NCS), Vanguard (Pilot) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 15, 2010, pages 69680–69681, and allowed 60 days for public comment. One comment was received. The comment questioned the value and utility of the proposed data collection, stating that this type of research is not needed. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Pilot Study for the National Children's Study *Type of Information Collection Request:* Revision. *Affected entities:* Households and individuals. *Types of respondents:* People potentially affected by this action are pregnant women, women age 18–49 years of age, their husbands or partners, and their children who live in selected areas within National Children's Study sites. Health care professionals, community leaders, and child care personnel are also potentially affected.

Frequency of Response: On occasion. See burden table for estimated number of annual responses for each respondent.

Need and use of information collection: The purpose of the proposed methodological study is to continue the Vanguard phase of the National Children's Study (NCS) to evaluate the feasibility, acceptability, and cost of recruitment strategies and study design elements for a prospective, national longitudinal study of child health and development. In combination, the sub-studies encompassed by the Vanguard Phase will be used to inform the design of the Main Study of the National Children's Study.

We propose to continue data collection among the 37 Vanguard Study locations up to and including the visit planned to take place when the sample children have reached 24 months of age. This would align study visits approved for the initial 7 Vanguard Study locations (which extend past the birth visit to include a 3-, 6-, 9-, 12-, 18- and 24-month visit) with the study visits approved for the 30 additional Vanguard Study locations (which were initially proposed and approved up to and including the birth visit). Extending the data collection of the 30 additional Vanguard Study locations to 24 months of age would support rigorous, empirical evaluation of participant retention as it may relate to recruitment strategy. A strong understanding of how to encourage retention of study participants, particularly during the infancy and early childhood years, will be essential to planning the Main Study. Additionally, continuing data collection post-birth among the alternate recruitment strategy study locations allows us to generate additional data to inform the development of study visit procedures, both for future Vanguard Study efforts and the Main Study.

We also propose reintroduction of a limited set of study visit measures to all 37 of the Vanguard Study locations engaged in data collection. Recall that extensive measures, including biospecimens, were previously approved for use in the initial 7 Vanguard Study locations. When the additional 30 locations were added, we streamlined data collection to allow focus on improving recruitment rates. Now that we have the training for those new locations (and retraining for the initial locations) completed, it is an opportune time to reintroduce selected measures that have the benefit of field experience. That field experience has been used to improve their scientific robustness, burden, and cost. These improved measures now require field testing to best inform their suitability for the Main Study. Specifically, we would like to reincorporate a father interview; maternal blood and urine collection; infant cord blood collection; home tap water and dust collection; a pregnancy health care log; and an infant and child health care log. In addition to supporting further testing of refined items, including these measures in the Recruitment Substudy would result in a data collection scope more closely mirroring the anticipated scope of the Main Study, thereby allowing better gauge of data collection scope and